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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,455	02/01/2001	Willima S. Argraves	19113.0071U1	5273

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NEEDLE & ROSENBERG P C  
127 PEACHTREE STREET N E  
ATLANTA, GA 30303-1811

EXAMINER

WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/10/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/700,455

Applicant(s)

ARGRAVES ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 March 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION*****Status of Application, Amendments, and/or Claims***

The Information Disclosure Statement, received 22 February 2001 (Paper 5), has been entered into the record. Applicant's election with traverse of Invention V, (claims 30-34) in Paper No. 8 is acknowledged. Applicant traversed the restriction and argued that it would not constitute a serious burden to search several groups. However, Groups I-V were restricted properly because they comprise products which possess characteristic differences in structure and function. Furthermore, the methods claimed or used in Groups I-V are independent and distinct in that they are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps, and goals. Furthermore, Inventive Group V were properly restricted as pertaining to methods that are practiced with different materials for different purposes as detailed in Paper 6 (2 October 2002). In addition, since a complete search of the art includes a search of the art that renders an invention obvious as well as anticipatory, the additional searches required for examination of Inventions I-IV *with* Invention V would be extensive, thus presenting an undue burden for the examiner. Claims 1-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claim.

Claims 30-34 are under examination in the Instant Application.

**Informalities**

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***Filing History***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78); this includes reference to Provisional Application 60/085,556.

Appropriate correction is required.

***Claims***

Claims 30 and 33 are objected to because they depend from non-elected Claims.

Appropriate correction is required.

***Abstract***

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. It should consist of one paragraph of 25 lines or less and 150 words or less.

Appropriate correction is required.

**Claim Rejections/Objections**

***Claim Rejections - 35 USC § 112, second paragraph-indefiniteness.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

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Claims 30-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30-34 recite or encompass the term "holoparticle." This word is an undefined term which renders the claims indefinite. The term "holoparticle" is not defined in the literature and not defined in Claims 30-34. Furthermore, the Independent claims from which claims 30-34 depend are inconsistent in their presumed definition of the term.

Claims 33 and 34 recite the term "*the* polypeptide." There is insufficient antecedent basis for use of this phrase, especially in the singular, in light of the term being defined by Independent claims as having several possible molecular weights, for example: *40-50 kDa*, *120 kDa* or *400 kDa*.

Claims 30-34 are rendered indefinite because they define a polypeptide by molecular weight (see Claim 1, for example) without specifying the method by which the molecular weights were obtained; it is not known therefore, how pure the polypeptides are or how accurate the measurements were. Amending independent claims to recite a method of molecular weight measurement would be remedial.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30, 31, 33 and 34 are rejected under 35 U.S.C. 102(b) as being unpatentable over Mcknight, et al (1992, JBC, 267: 16778-16782). Mcknight, et al. disclose binding experiments in which specific binding of HDL ligand is measured in COS and BHK cells transfected with an HDL receptor (see Table 1). They also disclose data which shows increased expression of the HDL receptor in cells bathed in a cholesterol-rich medium, and increased specific binding as a result (page 12135). This reference meets the limitations of claims 30, 31, 33 and 34 of the instant Application in which a method of screening for ligands can include several assays such as binding assays or measurements of HDL receptor expression, and in which the cell type is "a cell producing a functional HDL receptor".

Claims 30, 31, 33 and 34 are rejected under 35 U.S.C. 102(a) as being unpatentable over Matsumoto, et al (1997, JBC, 272: 16778-16782). Matsumoto, et al. disclose experiments in which specific binding of HDL ligand is measured in cells transfected with the HDL receptor- which is referred to as "*HB<sub>2</sub>*" in the reference (see Fig. 2). They also disclose data on the increased expression of *HB<sub>2</sub>* after stimulation of the cells with a differentiation factor as well as the consequent increase in ligand binding (see Fig. 4). This reference meets the limitations of claims 30, 31, 33 and 34 of the instant Application in which a method of screening for ligands can be a binding assay or a measurement of HDL receptor expression, and in which the cell type is "a cell producing a functional HDL receptor".

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Conclusion: Claims 30-34 are rejected for the reasons listed above. Claims 30 and 33 are objected to.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER

SLW

6/03/03